

## In the United States Court of Federal Claims

DANIELLE DOTSON, as parent and natural  
guardian of B.M., a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN  
SERVICES,

Respondent.

No. 17-vv-0637

(Filed Under Seal: July 10, 2025

Reissued for Publication: July 25, 2025)\*

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner.

Naseem Kourosh, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Defendant. With her on the briefs were Yaakov M. Roth, Acting Assistant Attorney General, C. Salvatore D'Alessio, Director, Heather L Pearlman, Deputy Director, and Voris E. Johnson, Jr., Assistant Director.

### **OPINION AND ORDER**

Meriweather, Judge.

Petitioner, Danielle Dotson, as parent and guardian of her minor son, B.M., seeks review of Special Master Moran's Entitlement Decision ("Decision"), denying her entitlement to compensation pursuant to the National Childhood Vaccine Injury Act of 1986. *See* 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act" or "Act"); *see generally* Pet'r's Mot. for Review, ECF No. 197 ("Mot."). Specifically, Ms. Dotson argues that the Special Master's fact finding concerning her burden of proof under prong one of the causation-in-fact test set forth in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), was arbitrary and capricious because the Special Master "erred . . . by not considering the [record] evidence . . . as a whole[] and [by] improperly imposing a heightened burden of proof of scientific certainty." Mot. at 1 ¶¶ 1–3. On March 11, 2025, Respondent, Secretary of Health and Human Services (the "Secretary") filed his Memorandum in Response to Petitioner's Motion for Review ("Response"), wherein he argues that the Special Master properly denied entitlement in this case because Ms. Dotson failed to "establish by preponderant evidence that the vaccination [] B.M. received" was the factual cause of his later-developed neurological condition. Resp't's Mem. in

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\* Pursuant to Vaccine Rule 18(b), this Opinion was initially filed on July 10, 2025, and the parties were afforded fourteen days to propose redactions. The parties did not propose any redactions and, accordingly, this Opinion is reissued in its original form for publication.

Resp. to Pet'r's Mot. for Review at 2, ECF No. 199 ("Resp."). Having considered the parties' oral arguments, reviewed the relevant filings,<sup>1</sup> the law, and for the reasons explained herein, the Court hereby **DENIES** Ms. Dotson's Motion for Review and **SUSTAINS** the Special Master's decision.

## BACKGROUND

### A. Factual Background

The Special Master set forth the factual and procedural background of this case, including summarizing B.M.'s medical records for the relevant time period, and both parties' expert reports, in his Decision. *See generally* Decision. For purposes of the pending motion, the Court will briefly summarize the relevant facts incorporated in that Decision, which are not in dispute.

B.M. was born on August 16, 2013, and on November 7, 2014, he received a ProQuad vaccine, which is a combined vaccination that "contains attenuated, but live, measles, mumps, rubella, and varicella<sup>2</sup> viruses." *Id.* at 2 n.2. On December 2, 2014, B.M. returned to his pediatrician, presenting with an intermittent fever that started the day before. *Id.* at 2. That pediatrician diagnosed B.M. as suffering from fever, seizures, and an ear infection. *Id.* at 3. Concerned by the seizures, B.M.'s pediatrician sent B.M. to the emergency room at Norton's Children's Hospital in Louisville, Kentucky. *Id.*

By the time he arrived at the emergency department, B.M. was actively seizing, and was quickly transferred to the pediatric intensive care unit. *See id.* B.M. remained in the hospital for approximately two weeks, during which time he underwent significant testing—including a brain CT, a spinal tap, a respiratory pathogen panel, blood work, a brain MRI, a CT angiogram, an echocardiogram, an MR angiogram, a von Willebrand related antigen panel,<sup>3</sup> a second brain MRI, and flow cytometry—and received varying treatments in an attempt to determine the cause, and reduce the severity of, his worsening neurological symptoms. *Id.* at 3–14.

Despite that extensive testing, B.M.'s treating physicians could not identify a clear

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<sup>1</sup> The following filings are relevant to this Order: Pet. for Compensation, ECF No. 1 ("Pet."); Am. Pet. for Compensation, ECF No. 64 ("Am. Pet."); Decision Den. Entitlement, ECF No. 194 ("Decision"); Mot., ECF No. 197; Resp., ECF No. 199. Throughout, page citations to documents in the record refer to the document's original pagination, unless the page is designated with an asterisk (*e.g.*, \*1), in which case the reference is to the pagination assigned by PACER/ECF.

<sup>2</sup> Varicella, colloquially referred to as the chickenpox, is a viral disease commonly associated with itchy, fluid-filled blisters. Sandeep Kumar & Haitham M. Saleh, *Varicella-Zoster Virus (Chickenpox)*, NIH (Apr. 27, 2025), <https://www.ncbi.nlm.nih.gov/books/NBK448191/>.

<sup>3</sup> Von Willebrand factor is a "glycoprotein" that assists with clotting. *See* Decision at 7.

explanation for his symptoms and “drew different conclusions.” *See id.* at 3–15, 11. Ultimately, B.M.’s physicians posited that there were “multiple possible etiologies,” *id.* at 12, which could explain his symptoms, and made their “[b]est estimate[s]” as to B.M.’s diagnosis, *id.* at 14, including considering vasculitis<sup>4</sup> and coronavirus OC-43,<sup>5</sup> which B.M. tested positive for, *see id.* at 4, among other potential causal diagnoses. And although B.M.’s physicians considered the possibility that the varicella component of his earlier vaccination could have contributed to B.M.’s symptoms, ultimately, all tests for the presence of the varicella virus were negative. *See id.* at 9, 45 (noting that Dr. Gershwin agreed “there is no evidence of infection”); Mot. at 39 (“Neither party to this case has proposed that B.M. got infected with chickenpox.”).

On December 15, 2014, B.M. was discharged from Norton’s Children Hospital to a rehabilitation hospital. *See* Decision at 15. On December 19, 2014, B.M. was readmitted to the hospital due to a high fever. *See id.* Following his second hospital discharge, B.M. was readmitted for rehabilitation, where he “received daily physical, occupational, and speech therapy.” *Id.* For the remainder of 2015, B.M. continued this therapy and underwent additional testing. *See id.* at 15–17. B.M.’s parents reported that he “was making significant gains in development . . . [h]owever, he [still] could not walk independently,” and his physicians posited that B.M. would likely “have long-term motor deficits” as a result of his ordeal. *Id.* at 16–17.

## **B. Procedural Background**

On May 15, 2017, Ms. Dotson filed her Petition for Compensation, wherein she alleged that various vaccines caused B.M. to suffer acute disseminated encephalomyelitis (“ADEM”),<sup>6</sup> which she supported by subsequently filing B.M.’s medical records and various affidavits. *See id.* at 17 (citing Pet.). The Secretary “challenged Ms. Dotson’s claim that B.M. suffered from ADEM and argued that, even if B.M. did suffer from ADEM,” the record evidence was insufficient to support a finding that any of the vaccines B.M. received was the factual cause of B.M.’s alleged ADEM diagnosis because “Ms. Dotson did not present expert opinion linking the vaccination to the alleged condition.” *Id.* (citing Resp’t’s Rep., ECF No. 20). Accordingly, the Special Master issued instructions for expert reports, but Ms. Dotson failed to timely submit her

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<sup>4</sup> Vasculitis involves inflammation of the blood vessels, which can cause organ and tissue damage. *See Vasculitis*, Mayo Clinic (Feb. 5, 2025), <https://www.mayoclinic.org/diseases-conditions/vasculitis/symptoms-causes/syc-20363435>. There are multiple types of vasculitis, most of which are uncommon. *See id.*

<sup>5</sup> “OC-43” is one variant of the common human coronavirus, which usually causes mild to moderate upper-respiratory-tract illnesses. *See Common Human Coronavirus*, CDC, <https://www.cdc.gov/coronavirus/downloads/Common-HCoV-fact-sheet-508.pdf> (last visited July 9, 2025). “This strain of the coronavirus differs from the strain that caused the pandemic.” Decision at 4.

<sup>6</sup> ADEM is a rare neurological condition causing central nervous system inflammation. *See Acute Disseminated Encephalomyelitis (ADEM)*, Cleveland Clinic (May 30, 2023), <https://my.clevelandclinic.org/health/diseases/14266-acute-disseminated-encephalomyelitis-adem>. ADEM can be caused by both viral and bacterial infections. *See id.*

expert reports. *See id.* (citing Order Regarding Expert Reps., ECF No. 22).

Nearly a year later, following repeated extensions, *see* ECF Nos. 27, 29, 32, 35, 41, Ms. Dotson still had not filed any expert reports; thus, the Secretary sought dismissal based on the lack of those reports. *See* Decision at 18 (citing Mot. to Dismiss, ECF No. 43). Ms. Dotson's counsel notified the Special Master that he would file a report from Lawrence Steinman shortly, and, based upon that representation, the Special Master denied the Secretary's motion, affording Ms. Dotson additional time to file Dr. Steinman's expert report. *Id.* (setting January 7, 2019 as the deadline for Ms. Dotson's expert reports). After another extension, Ms. Dotson finally filed her expert "report" on April 22, 2019—not from Dr. Steinman as she initially represented—but from M. Eric Gershwin. *Id.* (citing Ex. 15, ECF No. 53-1).

### **1. Dr. Gershwin's Initial Expert Reports**

In Dr. Gershwin's first "report," a two-page letter, he did not opine that any vaccination harmed B.M., nor did he present any conclusions as to a potentially causative medical theory. *See* Ex. 15 at 1–2; Decision at 18. Rather, he stated that he "required additional information," as described within that two-page letter, to "be in a better position to prepare a report." Ex. 15 at 1–2; Decision at 18. The Special Master issued a Show Cause Order, warning Ms. Dotson that her case may be dismissed for failure to prosecute because although Ms. Dotson "ha[d] been obligated to file an expert report for a significant time," she had failed to do so. Order to Show Cause at 1, ECF No. 54. As the Special Master noted in that Order, Dr. Gershwin's "report," "at its basic level" did not attempt to comply with the instructions for expert reports; did not opine that any vaccination harmed B.M. in any manner; and Ms. Dotson did not "present any plan by which she would obtain the information Dr. Gershwin ha[d] requested." *Id.* at 2. The Special Master found that letter was so rudimentary, so conclusory, and so unsupportive of Ms. Dotson's case, that he queried whether it had even been "intended for submission to the Court." *Id.*

Thereafter, Ms. Dotson filed a six-page report from Dr. Gershwin dated May 14, 2019, *see* Ex. 18, ECF No. 55-1, wherein he "opined that a varicella vaccine caused B.M. to suffer vasculitis," and stated that he was "concerned about two potential factual errors in the medical records that will lead to incorrect interpretation of the data and therefore an incorrect diagnosis in this youngster." Decision at 18–19 (quoting Ex. 18 at 4–6, ECF No. 55 (discussing two perceived errors, namely: (1) that B.M. did not have an immune deficiency; and (2) that B.M. did not suffer from an infection with a coronavirus)).

After the Secretary filed a second motion to dismiss, once again arguing that Ms. Dotson "failed to meet the requirements for compensation for a causation-in-injury claim" because "Dr. Gershwin's reports [were] patently insufficient to meet [her] burden of proof," Mot. to Dismiss at 3, ECF No. 56, Ms. Dotson added another report from Dr. Gershwin. *See* Ex. 40, ECF No. 61. That supplemental report "is approximately one page. . . . Dr. Gershwin wrote approximately one sentence on *Althen* prong one and two sentences on *Althen* prong two." Decision at 19 (noting that the "balance of the report was about *Althen* prong three"). Although the Special Master "stretched what Dr. Gershwin had written to understand that Dr. Gershwin may have been proposing a theory based upon either a varicella infection or hypersensitivity reaction," *id.* at 20 (quoting Order to Show Cause, ECF No. 62), the Special Master concluded that neither theory

supported Ms. Dotson's case. *Id.* at 19–20 (citing Order to Show Cause, ECF No. 62). The Special Master concluded the first causative theory was “problematic” because “although the varicella vaccine might lead to a varicella infection as a matter of theory, Ms. Dotson could not prevail upon this theory” because, as Dr. Gershwin himself acknowledged, “there is no evidence of infection.” *Id.* at 20 (citing Ex. 18 at 4). The Special Master similarly concluded that Dr. Gershwin's hypersensitivity reaction theory was equally “incapable of resulting in . . . compensation to Ms. Dotson because: (1) ‘Dr. Gershwin ha[d] not cited evidence that B.M. suffered an allergic reaction’; and (2) ‘the latency between the vaccination and the date of hospitalization (25 days) appears to exceed the amount of time [] for an allergic reaction to manifest.’” *Id.* (quoting Order to Show Cause at 4, ECF No. 62) (cleaned up). “Thus, Ms. Dotson was given another opportunity to present a comprehensive, complete, and reliable report from Dr. Gershwin,” and was “directed to have Dr. Gershwin comply with the instructions.” *Id.* (cleaned up).

Although “Ms. Dotson attempted to comply,” *id.*, with the Special Master's second Show Cause Order by filing another, approximately eight-page report from Dr. Gershwin, *see* Ex. 47, ECF No. 63-1, that report “was not a model of clarity.” Decision at 20. Indeed, “Dr. Gershwin copied much of the material from his previous reports.” *Id.* (identifying the ways in which Exhibit 47 is duplicative). The Special Master found this report so conclusory that “discerning a[ny medical] theory . . . is difficult.” *Id.* Dr. Gershwin dedicated a scant, four paragraphs to his “Theory, *Althen* 1.” *See id.* The Special Master summarized Dr. Gershwin's theory in his Decision as follows—

[As] Dr. Gershwin wrote: “The ‘theory’ is that Varicella antigens, whether from a live virus or from a live viral Varicella vaccine can cause CNS vasculitis. The cause and effect relationship between the Varicella antigen and CNS vasculitis is known and accepted by the medical community.” For the proposition, that the medical community accepts this relationship Dr. Gershwin cited a series of case reports as well as one article, Wise. Under the heading, “*Althen* III,” Dr. Gershwin wrote another paragraph and within this paragraph, Dr. Gershwin discussed timing in the context of molecular mimicry.

*Id.* at 20–21 (internal citations omitted). Following Dr. Gershwin's latest report, which the Special Master initially found was at least “adequate,” Ms. Dotson amended her petition to allege that B.M.'s varicella vaccine caused B.M. to suffer from vasculitis. *Id.* at 21 (citing Am. Pet.).

## **2. Dr. Kruer's Initial Expert Reports**

The Secretary responded to Dr. Gershwin's opinions by presenting an approximately four-page report from Dr. Kruer, wherein he requested original images of various studies and opined that: (1) B.M. likely suffered an infection with a primary coronavirus; (2) “a diagnosis of vasculitis was never confirmed”; and (3) B.M. suffered a primary immunodeficiency. *Id.* (citing Ex. C, ECF No. 70-1). After obtaining those requested diagnostic images, Dr. Kruer submitted a supplemental report, wherein he contended that Dr. Gershwin failed to “proffer[] a theory of causality,” and that it was “far more likely than not B.M.'s symptoms were due to the Coronavirus OC43 in the context of his underlying immunodeficiency.” *Id.* (quoting Ex. P at 3–



4, ECF No. 77-1).

### **3. Dr. Wilson's Initial and Dr. Gershwin's Supplemental Expert Reports**

Thereafter, Ms. Dotson submitted a seven-page report from David Wilson. *See* Ex. 54, ECF No. 90-1; Decision at 22. Based on his review of various imaging studies and a “limited amount of clinical information,” Dr. Wilson acknowledged that “this [was] a challenging case” and concluded that “the most likely explanation for B.M.’s condition was a vasculopathy<sup>7</sup> which may have been of infectious or immunogenic origin; however, this vasculopathy was almost certainly not caused by the cited pathogen OC43.” Decision at 22 (quoting Ex. 54 at 2–4) (internal citations omitted). In reaching this conclusion, Dr. Wilson suggested a number of different possible diagnoses that might explain B.M.’s symptomology including: (1) a vasculopathy; (2) a cerebritis/cerebellitis<sup>8</sup> caused by an infectious agent; (3) acute demyelinating injury either ADEM or acute hemorrhagic encephalomyelitis<sup>9</sup> (“AHEM”); or (4) an embolic stroke. *See id.*

In conjunction with Dr. Wilson’s report, Ms. Dotson submitted another one-page report from Dr. Gershwin, wherein he largely “agree[d] with Dr. Wilson’s opinions and maintains his previously expressed opinions,” which he presented in an abbreviated format, *i.e.*, a bulleted list. *See id.* (citing Ex. 76, ECF No. 88).

### **4. Dr. Zucconi's Initial and Dr. Kruer's and Dr. Gershwin's Supplemental Expert Reports**

On January 6, 2021 the Secretary filed a six-page supplemental report from Dr. Kruer, wherein he largely “agree[d] with Dr. Wilson’s assessment[] [that] B.M.’s neuroimaging [was] highly unusual” because that imaging “is not ‘typical’ of anything.” *Id.* at 22–23 (quoting Ex. X at 1, ECF No. 95-1) (noting that “Dr. Kruer’s opinions were directed to Dr. Wilson” because Dr. Kruer concluded that “Dr. Gershwin’s report did not contain any new assertions”). Given B.M.’s atypical diagnostic imaging, Dr. Kruer posited that “we are very likely [] dealing with either a rare disease, [] an atypical manifestation of a common disease, or some combination of the two.” *Id.* at 23 (quoting Ex. X at 1). After accounting for this caveat, Dr. Kruer reiterated his earlier

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<sup>7</sup> Vasculopathy is a general term that refers to any disease or abnormality affecting the blood vessels. *See Vascular Disease (Vasculopathy)*, Cleveland Clinic (March 22, 2022), <https://my.clevelandclinic.org/health/diseases/17604-vascular-disease>.

<sup>8</sup> Cerebritis is a type of encephalitis involving inflammation of the cerebrum, the largest part of the brain. *See Encephalitis*, Mayo Clinic (May 16, 2024), <https://www.mayoclinic.org/diseases-conditions/encephalitis/symptoms-causes/syc-20356136>. Cerebellitis is another type of encephalitis involving inflammation of the cerebellum, the part of the brain largely responsible for controlling muscle movement. *See id.*

<sup>9</sup> AHEM is a rare, central nervous system disease characterized by rapid and progressive inflammation of the brain’s white matter. *See* Decision at 21 (citing Ex. 54 at 6).

opinion that “the most likely diagnosis” is “an atypical coronavirus OC43 encephalitis in the context of an underlying immunodeficiency,” the bases for which he then explained in greater detail in the remainder of his report. *Id.* (citing Ex. X at 1–5). Within that report, Dr. Kruer also opined that Dr. Gershwin’s and Dr. Wilson’s reports were insufficient to show that the varicella vaccine caused B.M. to suffer vasculitis as opposed to a coronavirus infection. *Id.* (citing Ex. X at 5–6).

Ms. Dotson submitted another two-page report from Dr. Gershwin, wherein Dr. Gershwin “agreed B.M.’s symptomologies are unusual” but ultimately maintained that such symptomologies “are consistent with a [] vasculopathy.” *Id.* (citing Ex. 77 at 2, ECF No. 99-1).

On May 21, 2021, the Secretary filed a two-page report from Dr. Zucconi, which addressed why a varicella infection was unlikely and why the imaging supports acute viral encephalitis, as well as an additional report from Dr. Kruer, which challenged Dr. Gershwin’s conclusion that a diagnosis of vasculopathy was most likely. *Id.* at 23 (citing Ex. Y, ECF No. 106-1; Ex. Z, ECF No. 107-1).

### **5. Dr. Shafrir and Additional Expert Testimony**

Given the Special Master’s “interest in allowing Ms. Dotson to present her evidence” he “permitted [her] to add another expert”; thus, on December 20, 2021, Ms. Dotson submitted an approximately 50-page report from Dr. Shafrir. *Id.* at 24. As the Special Master noted, the bulk of this report, approximately 41 pages, merely summarized B.M.’s medical records through 2016. *See id.* (citing Ex. 84, ECF No. 124-1). In the remainder of that report, Dr. Shafrir opined that the three most likely potential causative diagnoses were ADEM, encephalitis, and vasculitis, and concluded that, of these three possible diagnoses, vasculitis was the most likely. *See id.* (citing Ex. 84 at 43–45). The Special Master found that although Dr. Shafrir generally concurred with Dr. Gershwin that the varicella vaccine was the most likely cause of the vasculitis, “Dr. Shafrir’s opinion as to a potential causal connection between the varicella vaccine and the vasculitis was not particularly robust.” *Id.* (citing Ex. 84 at 44–45) (noting that “Dr. Shafrir declined to address immunological parts of Dr. Kruer’s second report” and “[l]ikewise . . . did not discuss the radiology [] addressed by Dr. Wilson and Dr. Zucconi”).

The Secretary responded by filing a pair of supplemental reports from Dr. Zucconi and Dr. Kruer. *See id.* (citing Ex. AA, ECF No. 131-1; Ex. BB, ECF No. 132-1). Unsurprisingly, given Dr. Shafrir’s failure to comment on B.M.’s radiology results, Dr. Zucconi maintained his initial conclusion that B.M. had acute viral encephalitis caused by a coronavirus infection. *See id.* And Dr. Kruer’s six-page report responded to Dr. Shafrir “nearly paragraph-by-paragraph.” *Id.* (citing Ex. BB).

In a May 4, 2022 status conference, Ms. Dotson represented that there were no remaining expert opinions to be proffered in this case; accordingly, the Special Master issued a briefing order. *See id.* at 25 (citing Order, ECF No. 135). Despite this representation, Ms. Dotson filed an additional five-page report from Dr. Shafrir just one week after that briefing order was issued, which the Special Master noted “criticizes Dr. Kruer with language that is potentially inflammatory.” *Id.* at 25 n.14 (citing Ex. 99 at 3, ECF No. 138-1). The Secretary objected to Dr.

Shafir's report, but the Special Master overruled that objection, allowing the report to remain in the record, in part, because "the Secretary would not be prejudiced" and "could respond with more reports." *Id.* at 25.

The Secretary filed one last report from Dr. Kruer in response, wherein Dr. Kruer refutes Dr. Shafir's contentions. *See id.* at 26 (citing Ex. CC, ECF No. 151-1). The parties proceeded to briefing the issues, including the threshold dispute concerning the appropriate diagnosis for B.M., with Ms. Dotson "convinced" that the appropriate diagnosis was vasculitis and the Secretary alternatively contending that B.M. suffered from encephalitis. *Id.* at 27 (quoting Pet'r's Br. at 1, ECF No. 157).

#### **6. The Special Master's Decision Denying Entitlement and Ms. Dotson's Instant Motion**

In his Decision, the Special Master, after first assuming for purposes of his argument that B.M.'s ultimate diagnosis *was* vasculitis,<sup>10</sup> *see id.* at 30, concluded that "Ms. Dotson [] failed to meet all the elements necessary to show that the varicella vaccine was the cause-in-fact of (an assumed) vasculitis." *Id.* In reaching this conclusion, the Special Master took the "unusual step" of allowing Ms. Dotson multiple opportunities to clarify her causative theory as described above, *see id.* at 36, then carefully and comprehensively reviewed all of Ms. Dotson's submitted expert reports and literature. *See id.* at 31–42. The Special Master ultimately found that Ms. Dotson failed to present *any* theory causally connecting the vaccine at issue to B.M.'s assumed vasculitis as required under *Althen* prong one. *See id.* at 35 ("Ms. Dotson had one final chance to identify the theories she was asserting by filing a reply brief. However, she was silent."). Accordingly, the Special Master denied entitlement, concluding that Ms. Dotson had not met her *Althen* prong one burden of proof because she failed to establish by preponderant evidence that B.M.'s November 7, 2014 vaccination caused him to develop the assumed vasculitis. *See id.*

On February 10, 2025, Ms. Dotson filed her Motion for Review, arguing that the Special Master: (1) acted arbitrarily and capriciously when making fact findings concerning Ms. Dotson's *Althen* prong one proof; (2) erred by not "considering the evidence on the record as a whole"; and (3) erred by improperly heightening Ms. Dotson's burden of proof to require "scientific certainty" rather than preponderance. *See Mot.* at 2. The Secretary contends that the Special Master, after conducting a "thorough review of the record" and after "thoughtfully weigh[ing] [all] the evidence," "properly denied entitlement" in this case. *Resp.* at 2. On June 20, 2025, the Court held oral argument on Ms. Dotson's Motion.

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<sup>10</sup> The Federal Circuit has held that a special master may, in the unusual case where the alleged injury is disputed, "first determine which injury was best supported by the evidence in the record before applying the *Althen* test." Decision at 30 (quoting *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010)). Although the Secretary "maintains . . . that [the] alleged diagnosis of vasculitis was not preponderantly established," the Secretary proceeds to "address[] [Ms. Dotson's] arguments on appeal based upon the Decision as issued." *Resp.* at 4 n.2. Given that Ms. Dotson does not contend the Special Master's threshold determination was in error, the Court proceeds on the assumption that the alleged injury in this case is vasculitis.



## LEGAL STANDARD

“Under the Vaccine Act, the Court of Federal Claims reviews the decision of a special master to determine if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1350 (Fed. Cir. 2008) (citing *Althen*, 418 F.3d at 1277). In Vaccine Act cases, this Court uses three distinct standards of review—fact findings are reviewed under the “arbitrary and capricious” standard; legal conclusions are reviewed de novo under the “not in accordance with the law” standard; and discretionary rulings under the “abuse of discretion” standard. *Munn v. Sec’y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992) (cleaned up).

The arbitrary and capricious “standard of review [applicable to vaccine cases] is uniquely deferential for what is essentially a judicial process,” and the Federal Circuit has warned against “second guess[ing] the Special Master[’]s fact-intensive conclusions,” particularly in those cases “in which the medical evidence of causation is in dispute.” *Hodges v. Sec’y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). “The law is settled that this Court cannot substitute its judgment for that of the Special Master merely because it might have reached a different conclusion.” *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009) (cleaned up); see *Broekelschen*, 618 F.3d at 1345. Thus, this Court “does not reweigh the factual evidence, assess whether the Special Master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses.” *Broekelschen*, 618 F.3d at 1349 (cleaned up). “If [a] special master has considered the relevant evidence of record, drawn plausible inferences[,] and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.” *Hines v. Sec’y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). Accordingly, this Court should not find that a special master’s fact conclusions are arbitrary and capricious unless they are “so implausible that [they] could not be ascribed to a difference in view.” *Id.* at 1527 (cleaned up). Indeed, if a special master’s “conclusion is based on evidence in the record that is not wholly implausible, [this Court is] compelled to uphold that finding as not being arbitrary or capricious.” *Cedillo v. Sec’y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010); see also *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000).

## DISCUSSION

### **I. The Special Master’s Fact Conclusions Under *Althen* Prong One Were Rational and Well-Supported.**<sup>11</sup>

The Vaccine Act, enacted in 1986, created the National Vaccine Injury Compensation Program, through which claimants can petition to receive compensation for vaccine-related injuries or death. See generally 42 U.S.C. § 300aa-10(a). Under the Act, there are two ways a

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<sup>11</sup> This section addresses Ms. Dotson’s arguments that the Special Master’s “fact finding in relation to [her] *Althen* prong 1 [sic] proof was arbitrary and capricious.” Mot. at 2. Accordingly, the Court reviews the Special Master’s findings of fact under that “uniquely deferential” standard of review. *Hodges*, 9 F.3d at 961; see also *Munn*, 970 F.2d at 870 n.10.

petitioner can establish causation and thus qualify for compensation. First, a petitioner may establish that the vaccinee, after receiving a designated vaccine, suffered an injury listed on the Vaccine Injury Table within the requisite time period—commonly called a “Table Injury,” *see* 42 C.F.R. § 100.3(a)—in which case causation is presumed. *See* 42 U.S.C. § 300aa-11(c)(1). Alternatively, if a petitioner claims entitlement for an injury *not* listed in the Vaccine Injury Table, *i.e.*, an “Off-Table case,” the petitioner must instead prove that the vaccination was the cause-in-fact (“actual causation” or “causation in fact”) of the vaccinee’s asserted injury. *See id.* § 300aa-11(c)(1)(C)(ii)(I).

The Federal Circuit has long affirmed that the standard for proving causation in fact under the Vaccine Act is the same as the standard for proving “legal cause” in the general torts context. *See Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *de Bazan*, 539 F.3d at 1351. Specifically, the Federal Circuit has “adopt[ed] the Restatement rule for purposes of determining vaccine injury,” and “[a vaccine] is the ‘legal cause’ of harm if that [vaccine] is a ‘substantial factor’ in bringing about the harm, and [if] that [] harm would not have occurred but for the [vaccination].” *Shyface*, 165 F.3d at 1352 (citing Restatement (Second) of Torts § 431(a) (Am. L. Inst. 1965)). To establish that a vaccine is a “substantial factor” in bringing about the alleged harm, the petitioner in an “Off-Table Injury” case such as this one must satisfy the three-prong test first articulated in *Althen* and establish—

by preponderant evidence that the vaccination brought about [B.M.’s] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

*Althen*, 418 F.3d at 1278; *see also Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1355 (Fed. Cir. 2019); *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010). It is well-settled that a petitioner must prove “each of the three *Althen* prongs by a preponderance of the evidence,” *Boatmon*, 941 F.3d at 1355, and that “failure to establish any one prong is dispositive.” *Exum v. Sec’y of Health & Hum. Servs.*, 175 Fed. Cl. 681, 702 (2025).

**A. The Special Master Carefully Weighed and Considered All Relevant Evidence to Support His Well-Reasoned Findings.**

Ms. Dotson contends that the Special Master rejected her *Althen* prong one evidence “out of hand,” without offering any “reasons,” “explanation,” or “foundation.” Mot. at 27–29. The Court disagrees. The Special Master afforded Ms. Dotson repeated opportunities to support her claim, “drew generous inferences in [her] favor,” Resp. at 6, exhaustively reviewed Ms. Dotson’s briefing and the evidence (even in those circumstances, where it was questionable whether he was required to do so), and rationally supported his findings in support of his determination that Ms. Dotson failed to meet her burden under *Althen* prong one. *See Althen*, 418 F.3d at 1278. Accordingly, “reversible error will be extremely difficult to demonstrate.” *Hines*, 940 F.2d at 1528.

First, the Special Master did not reject Dr. Gershwin’s reports “out of hand,” Mot. at 29,

rather, he undertook a “painstaking review” of those reports, “for anything resembling a coherent theory,” Resp. at 8, but ultimately concluded that Dr. Gershwin’s “attempts to put forward a minimally competent medical theory fell well short.” Decision at 31. As noted above, Dr. Gershwin’s first “report,” a two-page letter, was patently insufficient, as, somewhat confoundingly, given that this a case seeking compensation for an alleged vaccine injury—*he did not opine that any vaccination harmed B.M.* See Ex. 15 at 1–2; Decision at 18. That first report was so conclusory, and so unsupportive of Ms. Dotson’s case, that the Special Master questioned whether it had even “be[en] intended for submission.” Order to Show Cause at 2, ECF No. 54. Dr. Gershwin’s second report was equally “problematic.” Decision at 20. Although the Special Master, again, afforded Dr. Gershwin leniency, “stretch[ing] what Dr. Gershwin had written” to understand that Dr. Gershwin was proposing either a varicella infection or a hypersensitivity reaction theory, the Special Master concluded neither of those theories were viable as presented, *id.* at 19–21 (quoting Order to Show Cause, ECF No. 62), in part, because as Dr. Gershwin himself acknowledges, and Ms. Dotson concedes, “there is no evidence of [varicella] infection” here. *Id.* at 20 (citing Ex. 18 at 4).

Similarly, Dr. Gershwin’s third report, “copied much of the material” from his previous two reports, “was not a model of clarity,” and only included four, conclusory paragraphs under the heading “Theory, *Althen* I.” *Id.* at 20 (citing Ex. 47 at 5–6). In that report, Dr. Gershwin stated “[t]he ‘theory’ is that Varicella antigens, whether from a live virus or from a live viral Varicella vaccine can cause CNS vasculitis. The cause and effect relationship between the Varicella antigen and CNS vasculitis is known and accepted by the medical community.” Ex. 47 at 5–6 (citing, in support of this proposition, a series of case reports, and one article, the Wise article). Despite these clear deficiencies, again, the Special Master afforded significant leniency, interpreting this report as proposing a causative theory of “molecular mimicry” under *Althen* prong one and finding that third report sufficiently “adequate” for the case to proceed. Decision at 21. But Dr. Gershwin never explained or further elaborated on this theory beyond this cursory statement in his third report, that is—the “evidence and arguments regarding molecular mimicry [were] too general to be persuasive.” *Id.* at 42 (noting that Dr. Gershwin’s reports “at least mention the idea” of molecular mimicry and that “[h]is second report includes the phrase . . . ‘molecular mimicry’ in the context of *Althen* prong three”).

In *Orloski*, the Federal Circuit concluded that the Special Master did not err by refusing to consider the petitioner’s primary expert opinion which the Special Master determined was “too conclusory and underdeveloped to be persuasive.” *Orloski v. Sec’y Health & Hum. Servs.*, 839 Fed. Appx. 538, 541 (Fed. Cir. 2021). In that case, although the Special Master gave the petitioner “several opportunities to bolster her case and provide a more detailed expert report,” those reports the petitioner did submit “did not provide any reasoning for how or why [the vaccinations] would cause” the alleged injury. *Id.* at 541–42. Here, as in *Orloski*, the Special Master afforded Ms. Dotson multiple opportunities to supplement her reports, and specifically identified why the reports submitted were deficient. But Dr. Gershwin’s ultimate submissions never articulated “any reasoning for how or why” the varicella vaccination could cause vasculitis. *Id.* The Special Master here was “entitled to require some indicia of reliability to support” Dr. Gershwin’s conclusory assertions, *Moberly*, 592 F.3d at 1324, he found none, and the Court declines to “reweigh th[at] [] evidence.” *Broekelschen*, 618 F.3d at 1349; *see also Pereira v. Sec’y of Health & Hum. Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (“An expert

opinion is no better than the soundness of the reasons supporting it.”).

And, “[f]or [the] sake of completeness,” the Special Master quoted Ms. Dotson’s<sup>12</sup> argument concerning Dr. Gershwin’s molecular mimicry causative theory in full—which he was able to do easily due to its conclusory nature—remarking that she “did not elaborate” on that argument, “included [a mere] one sentence from three [of the cited] articles,” and “without any descriptive information,” cited another eight articles. Decision at 33–34. The Special Master specifically noted that although Ms. Dotson discussed *Althen* prong one in her brief, she did so “in approximately two double-spaced pages,” and simply asserted, without support, that “[t]here is abundant evidence linking varicella to vasculitis,” and “[t]he literature treats it as a given.” *Id.* at 32. Notably, this is the same argument that Ms. Dotson quotes verbatim in her pending Motion. Compare Decision at 33, with Mot. at 17. The Special Master did not err by “conclud[ing] that there [was] simply too great an analytical gap between the data and the opinion proffered.” *Cedillo*, 617 F.3d at 1339.

The Special Master similarly exhaustingly examined the “primary piece of evidence,” in this case, the Wise article, which Dr. Gershwin cites in both his first and third reports. Decision at 36; see also Ex. 18 at 5; Ex. 47 at 5. As described by the Special Master, “[i]n this article, Robert P. Wise and his colleagues searched Vaccine Adverse Event Reporting System (“VAERS”) . . . [where] [t]hey found 15 cases of vasculitis . . . [a]mong [those] 15 vasculitis reports, 3 children . . . appeared to have Kawasaki syndrome, and 10 patients developed Henoch-Schönlein purpura within 7 weeks of vaccination.” Decision at 36 (citing Ex. 37 at 1272–75, ECF No. 59-3). The Special Master analyzed the Wise article in conjunction with a different study cited by the Secretary’s expert, Dr. Kruer, in response to the Wise article, and found both unpersuasive—“[t]he relative weakness of [Dr. Kruer’s cited] article does not elevate the value of Wise article.” *Id.* at 37 (criticizing Dr. Kruer’s cited article because “[u]pon] review of this article [he] did not readily identify any places in which the authors assessed whether the varicella vaccine can cause vasculitis”). The Special Master concluded that the Wise article should be afforded little weight because “Wise’s methodology of extracting data from the VAERS database is not reliable.” *Id.* The Special Master did not err in making that finding. Indeed, this “Court uniformly has upheld [a] [] Special Master’s concerns about the reliability of VAERS data,” *Analla v. Sec’y of Health & Hum. Servs.*, 70 Fed. Cl. 552, 558 (2006) (collecting cases), and found that VAERS data “has extremely limited value to prove causation due to the manner in which it is collected, the lack of confirmation of the reported information[,] and the lack of any systematic analysis.” *Capizzano v. Sec’y of Health & Hum. Servs.*, 63 Fed. Cl. 227, 231 (2004) (vacated on other grounds); see also *Manville v. Sec’y of Health & Hum. Servs.*, 63 Fed. Cl. 482, 494 (2004) (affirming special master’s finding that a “VAERS report can be filed by anyone, thereby bringing into question the quantity and quality of the information gathered and creating the possibility of bias”). Accordingly, the Special Master’s determination that the VAERS evidence should be afforded little to no weight was both proper and reasonable. See *Ryman v. Sec’y of Health & Hum. Servs.*, 65 Fed. Cl. 35, 43 (2005).

Next, the Special Master, acting “out of an abundance of caution” even reviewed those

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<sup>12</sup> Ms. Dotson’s argument is taken verbatim from Dr. Gershwin’s June 18, 2019 expert report. Compare Decision at 33 (quoting Pet’r’s Status Report, ECF No. 180), with Ex. 40 at 1.



articles Ms. Dotson cited in her briefing “without any explanation of their relevance[,] [which] could [have] justif[ied] [his] striking th[ose] articles.” Decision at 34 n.23; *see also Sheller v. Sec’y of Health & Hum. Servs.*, 121 F.4th 1301, 1309 (Fed. Cir. 2024) (concluding that “the Special Master did not abuse his discretion in striking [certain] medical articles” once he “assessed the relevance of each medical article and only struck those determined not to be relevant”). Despite, once again, affording Ms. Dotson this additional leniency, the Special Master here still concluded that those cited articles did not support Ms. Dotson’s theory of causation because they were duplicative, “focus[ed] on conditions not at issue in Ms. Dotson’s case,” and “concern[ed] [] different vaccine[s]” than the vaccine alleged to have caused B.M.’s vasculitis. *Id.* (discussing Ex. 71, ECF No. 88-6, and Ex. 73, ECF No. 88-8, which focused on possible correlations between the varicella vaccine and stroke and ADEM respectively and explaining that “Ms. Dotson has not persuasively explained why B.M.’s asserted condition [of vasculitis] is analogous to either” of those two conditions discussed by the proffered evidence) (also discussing Ex. 35, ECF No. 59-1, “a case report concerning a different vaccine,” *i.e.*, the herpes zoster vaccine). In other words, some of the materials Ms. Dotson put forth discussed neither the varicella vaccine nor vasculitis at all. *See H.L. v. Sec’y of Health & Hum. Servs.*, 715 Fed. App’x 990, 996 (Fed. Cir. 2017) (finding no error in a special master’s determination that certain articles were not persuasive when those “articles discuss circumstances that are not directly analogous to [the present] case”). The Special Master further found that Exhibit 35, the Puram case report, was unreliable because it “provide[s] little, if any, information helpful to determining causation [as] [it] present[s] only a temporal sequence of events in which the vaccination preceded an adverse health event.” Decision at 34–35 n.23; *see also K.O. v. Sec’y of Health & Hum. Servs.*, No. 13-vv-0472, 2016 WL 7634491, at \*11 (Fed. Cl. Spec. Mstr. July 7, 2016) (“The only Federal Circuit case to discuss the value of case reports in the Vaccine Program found no error in a special master’s giving the case reports little weight.”). The Special Master carefully weighed this evidence (even though he conceivably was not required to do so) to reach plausible conclusions. The Court declines to “second guess” the Special Master’s “fact-intensive” conclusions, which were well within his purview. *Hodges*, 9 F.3d at 961.

The Special Master proceeded to comprehensively review each of the remaining articles proffered by Ms. Dotson, and relied upon by her experts, in turn, including: the Nagel and Gilden article (Ex. 33, ECF No. 58-6); the Strauss article (Ex. 46, ECF No. 61-7); the Gilden article (Ex. 51, ECF No. 63-5); the Nagel and Bubank article (Ex. 34, ECF No. 58-7; Ex. 57, ECF No. 87-2); the Rojas article (Ex. 45, ECF No. 61-6); the Guillevin article (Ex. 41, ECF No. 61-2); the Celluci and Benesler article (Ex. 98, ECF No. 125-5); and the Twilt and Beneseler article (Ex. 87, ECF No. 124-4). *See* Decision 38–41. Although Ms. Dotson wrote “at least one sentence in the context of *Althen* prong one,” about these articles, the Special Master devotes three, single-spaced pages to his fulsome analysis. *Id.* at 41. The Special Master afforded these remaining articles little weight for varying reasons, including that some of those articles, like those articles discussed above, do not discuss the varicella vaccine or vasculitis. *See id.* at 40. For example, he observed that the “Rojas article has limited usefulness in providing a theory to explain how [the] varicella vaccine can cause vasculitis,” given that the authors “discussed how infections may induce autoimmune diseases through molecular mimicry[,] [t]hey detail evidence in approximately a dozen diseases, but none are vasculitis.” *Id.* He further noted that “Guillevin . . . did not discuss varicella as an inciting agent.” *Id.* at 41. Ms. Dotson takes issue with the Special Master’s approach, contending that he improperly “picked off each piece of [] evidence



individually.”<sup>13</sup> Mot. at 31. But this Court cannot imagine another way for the Special Master to have evaluated Ms. Dotson’s evidence other than to look at each article on its own merits. Rather, as the Secretary posits—“it would be error to *fail* to review the articles individually and to instead only consider the literature as an undifferentiated mass” because a special master must evaluate *all* the evidence in the record. Resp. at 14; *see also* Rule 8(b)(1), Vaccine Rules of the Office of Special Masters (requiring that the Special Master “must consider all relevant and reliable evidence”); *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 541 (2011) (“[C]onsistent with the duties imposed by the Vaccine Act, the task of a Special Master is to consider [all] the relevant evidence in the record.” (internal citations omitted)).

Ms. Dotson’s alternative argument<sup>14</sup> that the Special Master failed to review the evidence in the “record as a whole,” is similarly unpersuasive.<sup>15</sup> Mot. at 29, 31–33. That argument is undermined by Ms. Dotson’s contention that the Special Master diligently “picked off,” *id.* at 31, each piece of evidence one by one—if the Special Master reviewed each and every piece of record evidence, how could he have also failed to review the record in its entirety? There is simply no indication that the Special Master improperly excluded evidence or failed to consider Ms. Dotson’s proffered evidence either individually or collectively. Rather, as identified throughout this Opinion, the Special Master’s review was exhaustive, he acted permissively in affording Ms. Dotson additional opportunities to present her case, *see* Decision at 35, assumed certain arguments on Ms. Dotson’s behalf, *see id.* at 43, and evaluated evidence that potentially could have been stricken, *see id.* at 34 n.23. There is no basis to disturb the Special Master’s findings of fact on those grounds.

Finally, Ms. Dotson asserts that the Special Master erred by “ignor[ing]” that B.M.’s treating physicians “included the varicella vaccine in B.M.’s differential diagnosis.” Mot. at 29. But the Special Master did not ignore B.M.’s medical records—he cited them explicitly throughout his Decision. *See* Decision at 8, 11–14. While the Special Master took great care to relate all B.M.’s relevant medical history and contemporaneous treating physician notes, the Court notes that perhaps he could have included a more detailed *analysis* of those records within his Decision. Regardless of whether this Court may disagree with the weight afforded to that evidence, the Special Master was “not required to cite to [nor discuss] every piece of evidence so

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<sup>13</sup> To the extent that Ms. Dotson is arguing that the totality of these articles should have persuaded the Special Master, despite each of the articles’ individual deficiencies, the Court agrees with the Secretary that this argument is illogical. *See* Resp. at 14. “[T]he sum of many zeros is still zero.” *Id.*

<sup>14</sup> It is unclear whether Ms. Dotson, in making this argument, is asserting that the Special Master failed to abide by the Vaccine Act; whether she is asserting the Special Master failed to review the record evidence cumulatively, and therefore assigned that evidence inappropriate weight; or whether she is asserting that the Special Master improperly excluded certain evidence. The Court reviews these arguments *de novo*, under the arbitrary and capricious standard, and under the abuse of discretion standard respectively. *See Munn*, 970 F.2d at 870 n.10. Under any standard of review, Ms. Dotson’s argument is unavailing.

<sup>15</sup> *See supra* note 11 and accompanying text.

long as [he] conducts a detailed review of the testimony, medical records, and medical literature.” *Cozart v. Sec’y of Health & Hum. Servs.*, 126 Fed. Cl. 488, 495 (2016); *see also Simanski v. Sec’y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) (“[A] Special Master is not required to discuss every piece of evidence or testimony in his or her decision.” (collecting cases)). In fact, as the Federal Circuit has affirmed, this Court presumes that the Special Master reviewed all the evidence presented absent an explicit expression to the contrary. *Hazlehurst v. Sec’y of Health & Hum. Servs.*, 604 F.3d 1343, 1352 (Fed. Cir. 2010) (“[E]ven if the Special Master had made no explicit reference to the [referenced] evidence . . . we would presume that she considered that evidence.”).

Ultimately, the Special Master, after first generously assuming that Ms. Dotson also advanced a direct viral invasion theory that was only alluded to in one her articles, but never directly advanced by her experts, concluded that all of the “theories [presented] lack[ed] sufficient development” because “one sentence or two sentences [cannot] establish the soundness of any of them.” Decision at 43–44 (assuming that Ms. Dotson “intended to advance ‘viral infection’ as a theory to explain how the varicella vaccine can cause vasculitis,” “if only for the sake of advancing the analysis”). The Special Master gave Ms. Dotson and her experts every possible opportunity to make their case but found that the evidence presented fell far short of meeting Ms. Dotson’s burden. Ms. Dotson’s own attempt to show that the Special Master failed to consider all the evidence, by including block quotations of that allegedly un-reviewed evidence in her Motion, again only underscores that the Special Master committed no error here because he, in fact, considered each of those same pieces of evidence. *Compare* Mot. at 18–23 (citing Ex. 33 (Nagel); Ex. 34, ECF No. 58-7 (Nagel); Ex. 35, ECF No. 59-1 (Puram); Ex. 36, ECF No. 59-2 (Twilt); Ex. 37 (Wise); Ex. 41 (Guillevin); Ex. 45 (Rojas); Ex. 51 (Gilden); Ex. 87 (Twilt); Ex. 98 (Cellucci)), *with* Decision at 38–39 (discussing Ex. 33 (Nagel)), 39–40 (discussing Ex. 34 (Nagel)), 19 n.10 (discussing Ex. 36 (Twilt)), 34 n.23 (discussing Ex. 35 (Puram)), 36–37 (discussing Ex. 37 (Wise)), 40–41 (discussing Ex. 41 (Guillevin) and Ex. 45 (Rojas)), 39 (discussing Ex. 51 (Gilden)), 41 (discussing Ex. 87 (Twilt) and Ex. 98 (Cellucci)). Indeed, after a thorough review of the record evidence and the Special Master’s decision below, this Court has been unable to identify a single piece of relevant evidence that the Special Master failed to carefully consider, analyze, and weigh. *See Hines*, 940 F.2d at 1528.

In sum, the Special Master scoured the record for any evidence that might support Ms. Dotson’s claim, while affording Ms. Dotson multiple opportunities to correct the deficiencies he identified, but “simply found the evidence lacking.” Resp. at 11. He comprehensively considered and weighed both the expert reports and literature, alongside Ms. Dotson’s briefing, drew plausible inferences, and rationally concluded that Ms. Dotson’s theories were too unsubstantiated, vague, and undeveloped to carry her burden under *Althen* prong one. *See Hines*, 940 F.2d at 1528. Accordingly, this Court is “compelled to uphold that finding as not being arbitrary or capricious.” *Cedillo*, 617 F.3d at 1338.

## **II. The Special Master’s Conclusion that Ms. Dotson Failed to Satisfy her Burden of Proof Under *Althen* Prong One Was in Accordance with the Law.**

### **A. The Special Master Did Not Impermissibly Raise Ms. Dotson’s Burden of Proof.**

Ms. Dotson contends that the Special Master improperly heightened her *Althen* one prong burden of proof; arguing that the Special Master impermissibly required her to prove causation by “produc[ing] evidence . . . of scientific certainty” instead of mere preponderance.<sup>16</sup> Mot. at 33. Ms. Dotson is correct that “[t]he standard of proof required by the Act is simple preponderance of evidence . . . not scientific certainty.” *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991) (emphasis added) (“[I]t is not [petitioner’s] burden to disprove every possible ground of causation . . . nor must the findings of the [Special Master] meet the standards of the laboratorian.” (internal citations omitted)); *Althen*, 418 F.3d at 1280. In other words, “the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged.” *LaLonde v. Sec’y of Health & Hum. Servs.*, 746 F.3d 1334, 1338–39 (Fed. Cir. 2014) (“[T]he burden of showing something by a preponderance of the evidence . . . simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.”).

A special master improperly heightens a petitioner’s burden by *requiring* “objective confirmation that the vaccine administered is potentially [causative] [of] the injury alleged,” *Althen*, 418 F.3d at 1279, either through “identification and proof of specific biological mechanisms,” or presentation of “epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities.” *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280; *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). “[S]uch an approach is inconsistent with allowing the use of circumstantial evidence envisioned by the preponderance standard.” *Id.*

And as *Althen* clarifies, although “scientific certainty” is not the applicable standard of proof, a petitioner’s “theory of causation must [still] be supported by a reputable medical or scientific explanation.” *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379–80 (Fed. Cir. 2009); *see also Broekelschen*, 618 F.3d at 1345 (“[A] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the [vaccinee’s] case, although th[at] explanation need only be ‘legally probable.’”); *Knudsen*, 35 F.3d at 548 (requiring a “sound and reliable medical or scientific explanation”). Thus, neither a “special master [n]or [this] [C]ourt may [] make . . . a finding [of causation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1). Accordingly, the Federal Circuit has “consistently rejected theories that the vaccine only ‘likely caused’ the [alleged] injury and [has] reiterated that a ‘plausible’ or ‘possible’ causal theory does not satisfy the [preponderance] standard.” *Boatmon*, 941 F.3d at 1360 (collecting cases); *see also LaLonde*, 746 F.3d at 1339 (“[W]e have made clear that simply identifying a ‘plausible’ theory of causation is insufficient for a petitioner to meet [their] burden of proof.”); *Moberly*, 592 F.3d at 1322 (noting that the “traditional” standard is “more likely than not” and that “a [mere] plausible or possible causal link between the vaccine and the injury, [] is not the statutory

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<sup>16</sup> Ms. Dotson argues that the Special Master erred by improperly heightening her burden of proof, a legal argument. Accordingly, the Court reviews the Special Master’s conclusion as to the proper evidentiary burden de novo, but reviews those factual conclusions reached in assessing whether Ms. Dotson had met the applicable burden of proof under the arbitrary and capricious standard. *See Munn*, 970 F.2d at 870 n.10.

standard”).

Here, the Special Master did not impermissibly heighten Ms. Dotson’s burden of proof. Rather, the Special Master properly held Ms. Dotson to a preponderance standard, and simply found the evidence she presented insufficient to preponderantly establish “a medical theory causally connecting [the ProQuad] vaccination and [B.M.’s] injury.” *Althen*, 418 F.3d at 1278. Indeed, the Special Master correctly identified that Ms. Dotson was “required to establish her case by a preponderance of the evidence” and took care to note that “[d]istinguishing between preponderant evidence and medical certainty is important because a special master should not impose an evidentiary burden that is too high.” Decision at 29 (quoting *Andreu*, 569 F.3d at 1379–80). The Special Master also correctly stated, in accordance with controlling Federal Circuit precedent, that “[p]resenting a sound and reliable [medical] theory is essential to Ms. Dotson’s case” under *Althen* prong one. *Id.* at 35; *see also Andreu*, 569 F.3d at 1379; *Broekelschen*, 618 F.3d at 1345; *Knudsen*, 35 F.3d at 548 (requiring a “sound and reliable medical or scientific explanation”). “The Decision correctly articulated that standard here.” *Exum*, 175 Fed. Cl. at 704. In fact, “the Federal Circuit recently affirmed a different decision of the Chief Special Master in which he articulated the standard in nearly the same way.” *Id.* (citing *Kalajdzic v. Sec’y of Health & Hum. Servs.*, No. 23-cv-1321, 2024 WL 3064398, at \*2 (Fed. Cir. June 20, 2024)).

And although the Special Master repeatedly reminded Ms. Dotson of her obligation to present a viable causative theory, affording her multiple, additional opportunities to present such a theory, ultimately the “evidence Ms. Dotson [] advanced . . . f[ell] short of meet[ing] her burden.” Decision at 30, 36 (“After multiple rounds of expert reports and rounds of briefing, whether Ms. Dotson has disclosed any theory is debatable. Ms. Dotson was notified repeatedly that the presentation of any theory was not adequate. She did largely not cure this deficiency.”). In fact, even though “Ms. Dotson had one final chance to identify the theories she was asserting by filing a reply brief,” she failed to do so. *Id.* at 35.

Despite Ms. Dotson’s continued failure to put forth evidence sufficient to support *any* theory, the Special Master still thoughtfully, carefully, and deliberately reviewed all the evidence that Ms. Dotson did put forth, as discussed in more detail, *supra*, ultimately concluding that none of that evidence “carr[ie]d Ms. Dotson’s burden to demonstrate that the varicella vaccine can cause vasculitis.” *Id.* at 31–42. Given the Special Master’s careful consideration of the relevant record evidence, and the plausible inferences drawn therefrom, this Court declines to “reweigh the factual evidence” and declines to “[re]assess whether the Special Master correctly evaluated th[at] evidence” to support his conclusion that Ms. Dotson failed to put forth any viable causative theory. *Munn*, 970 F.2d at 871.

Contrary to Ms. Dotson’s argument, the Special Master could not have reasonably determined that Ms. Dotson preponderantly put forth a causative medical theory in this case because neither the Special Master nor this Court may “make . . . a finding [of causation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1). That is, once the Special Master rationally concluded that all of Ms. Dotson’s potential causative theories “were presented in such an abbreviated form that they are not sound and reliable,” he was obligated to find that she failed carry her burden under *Althen*

prong one. Decision at 42–43 (“[Ms. Dotson’s] theories lack sufficient development. One sentence or two sentences do not establish the soundness of any of them.”). It would have been error for the Special Master to find that Ms. Dotson had met her burden—after finding *all* the proffered evidence too vague, irrelevant, and implausible to support *any* causative theory—because such a holding would have been premised on nothing other than Ms. Dotson’s assertions alone. *See id.* at 45 n.33 (“Ms. Dotson presented negligible support for [her] theories.”). Indeed, the Federal Circuit has consistently affirmed that mere plausibility is insufficient to meet the preponderance of evidence standard. *See, e.g., Boatmon*, 941 F.3d at 1360; *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (“[P]etitioner must do more than demonstrate a ‘plausible’ or ‘possible’ causal link between the vaccination and the injury.”). *But see* Mot. at 15–17, 26, 29 (referencing a “plausible” medical theory). Accordingly, any such holding that Ms. Dotson’s causative theory was sufficient on this record would have improperly *lessened* Ms. Dotson’s burden of proof under controlling precedent. *See Boatmon*, 941 F.3d at 1360 (collecting cases); *LaLonde*, 746 F.3d at 1339 (“[S]imply identifying a ‘plausible’ theory of causation is insufficient for a petitioner to meet [their] burden of proof.”).

Ms. Dotson’s remaining arguments on this point fare no better.<sup>17</sup> Specifically, although Ms. Dotson argues that the Special Master improperly heightened her burden by requiring her to produce epidemiological studies to support her claim, *see* Mot. at 34, the record explicitly forecloses this argument. While it is true that the Special Master noted that “an affirmative epidemiological study could have helped Ms. Dotson establish that the varicella vaccine can cause vasculitis,” he did not in fact require Ms. Dotson to put forth such a study. Decision at 38. Instead, he clarified—despite Ms. Dotson’s insistence that the Wise article was epidemiological, he did not believe the Wise paper was an epidemiological study as it lacks the traditional characteristics of those studies—that “the lack of an epidemiological study does not doom the claim because a petitioner is not required to present an epidemiologic study.” *Id.* The Special Master further noted that: “the Wise study is not persuasive evidence for th[e] proposition” that the varicella vaccine can cause vasculitis—not because the Wise study is non epidemiological, but rather because the Wise study itself is unreliable—and cites another Special Master decision discussing, and discarding, that same study. *Id.* (citing *Stapleford v. Sec’y of Health & Hum. Servs.*, No. 03-vv-0234, 2009 WL 1456441, at \*8 (Fed. Cl. May 1, 2009) (“[T]he Wise article[] cannot reasonably be cited as evidence for a conclusion that the varicella vaccine can cause seizures.”)). Thus, the Special Master did not require Ms. Dotson to proffer epidemiological studies to support her claims, “he merely discounted the persuasiveness of the one proposed.” *Munoz v. Sec’y of Health & Hum. Servs.*, 174 Fed. Cl. 276, 289 (2024).

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<sup>17</sup> “In an attempt to show that the Special Master heightened her burden, [Ms. Dotson] brings up the Wise paper again and then engages in a hypothetical discussion regarding statistical significance and confidence intervals.” Resp. at 16–17. The Court agrees with Respondent that this argument, premised on pure conjecture and speculation, and “devoid of any citations,” is irrelevant to Ms. Dotson’s pending Motion, as it does not identify any evidence that the Special Master failed to review, nor does it argue that the Special Master misapplied the law. *See id.* at 17. The Court therefore declines to address it.



**B. Neither the Special Master nor the Secretary Was Required to Disprove Ms. Dotson’s Theory of Causation.**

At various points throughout her Motion, Ms. Dotson contends that the Special Master erred by not affirmatively disproving her theory of causation.<sup>18</sup> *See, e.g.*, Mot. at 27. For example, she states, “[w]hat evidence is in this record that SM Moran could rely on to counter this world class immunologist [and] all of the medical literature . . . ? The answer to this question is NOTHING.” *Id.* Ms. Dotson similarly faults the Secretary for failing to disprove her causative theory. *See id.* at 24 (arguing that the Special Master’s Decision should be reversed, in part, because Dr. Kruer failed to provide commentary on Dr. Gershwin’s medical theory);<sup>19</sup> *id.* at 27 (“Dr. Kruer provided no counter opinions.”); *id.* at 28 (referencing the lack of a “counter medical opinion”) (contending that none of the “hundreds of medical articles filed in this case . . . prove[] [] Dr. Gershwin is wrong”). In so arguing, Ms. Dotson “appears to misunderstand the burden of proof.” Resp. at 6. “[T]he caselaw is clear,” *id.*, “it is [Ms. Dotson’s] burden to prove causation” in the first instance. *W.C.*, 704 F.3d at 1359. “In Off-Table cases, petitioners bear the burden to prove actual causation.” *Bechel v. Sec’y of Health & Hum. Servs.*, 168 Fed. Cl. 602, 615 (2023). Neither the Secretary nor the Special Master bore “the burden of proving a *prima facie* case.” *Doe v. Sec’y of Health & Hum. Servs.*, 601 F.3d 1349, 1356 (Fed. Cir. 2010).

**C. The Secretary Was Not Required to Show an Alternative Cause.**

Ms. Dotson argues that the Special Master’s decision should be reversed because the Secretary failed to present “any viable alternate cause.”<sup>20</sup> Mot. at 38. Again, Ms. Dotson is mistaken on the law—because the Special Master concluded that Ms. Dotson failed to meet her burden of proof, and because this Court concludes that determination was well-supported and in accordance with the law—“the Secretary [wa]s not obligated to present an alternative cause.” Decision at 47.

It is well-settled that the framework articulated in *Althen* is a burden-shifting framework. *See Bechel*, 168 Fed. Cl. at 616 (“If a petitioner presents adequate evidence on the three essential aspects of causation, and thus makes a *prima facie* case for liability, the burden shifts to the Government to prove, by a preponderance of evidence, an alternate cause of the alleged

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<sup>18</sup> The Court reviews this additional legal argument *de novo*. *See Munn*, 970 F.2d at 870 n.10; *supra* note 11.

<sup>19</sup> The Court notes that it might very well have been exceedingly difficult, if not impossible, for Dr. Kruer to provide substantive commentary refuting each of Dr. Gershwin’s contentions, although he did in fact attempt to do so, because as the Special Master noted, Dr. Gershwin’s attempts to “put forward a minimally competent medical theory fell well short.” Decision at 31. Indeed, it was Dr. Kruer’s opinion that Dr. Gershwin failed to “proffer[] [any] theory of causality” to which he *could* respond. *Id.* at 31–32 (quoting Ex. P at 3) (noting that Dr. Kruer opined that “petitioner has not offered any cogent theory of causation”).

<sup>20</sup> The Court reviews this additional legal argument *de novo*. *See Munn*, 970 F.2d at 870 n.10; *supra* note 11.

injury.”); *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). That is, the Secretary is obligated to “show[], also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine” if, and only if, petitioner first “satisfies [her] burden” to preponderantly meet the three *Althen* prongs. *LaLonde*, 746 F.3d at 1338. In other words, because Ms. Dotson “fail[ed] to establish a prima facie case, the burden [did] not shift to Respondent.” *Exum*, 175 Fed. Cl. at 702; *de Bazan*, 539 F.3d at 1354 (“[T]his latter showing [to preponderantly establish that the injury was caused by an alternate cause] is the government’s burden *once the petitioner has met her burden.*” (emphasis added)). Thus, the Secretary was not obligated to establish an alternate cause here.

### CONCLUSION

Although the Court both understands and appreciates the pain Ms. Dotson experienced watching her child suffer through a significant and life-altering medical ordeal, for the reasons set forth herein, the Court finds that the Special Master’s determination that Ms. Dotson failed to satisfy *Althen* prong one was neither arbitrary and capricious nor contrary to law. Ms. Dotson’s Motion for Review, ECF No. 197, is therefore **DENIED** and the Special Master’s decision is **SUSTAINED**. The Clerk shall enter **JUDGMENT** accordingly.

**IT IS SO ORDERED.**

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ROBIN M. MERIWEATHER  
Judge